UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DONNARAE GORDON and THOMAS GORDON, Plaintiffs	)	CIVIL ACTION NO. _____
V.		
JOHNSON & JOHNSON, INC., ETHICON, INC., and ETHICON, LLC., Defendants	)	

COMPLAINT AND JURY DEMAND

Plaintiffs, DonnaRae Gordon and Thomas Gordon, by and through their undersigned counsel, brings this action for damages against Defendants, Johnson & Johnson, Inc., Ethicon, Inc., and Ethicon, LLC, and alleges as follows:

I. PARTIES

A. Plaintiffs

1. Plaintiffs, DonnaRae Gordon and Thomas Gordon are citizens of West Boylston, Worcester County, Massachusetts.

B. Defendants

2. Defendant, Johnson & Johnson ("J&J") is a corporation with its worldwide headquarters located in New Brunswick, New Jersey. Johnson & Johnson organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its' pelvic floor repair products. Within J&J there are three sectors, medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The companies which comprise the Ethicon Franchise

are thus controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon LTD.

3. Defendant, Ethicon, Inc. ("Ethicon") is a wholly owned subsidiary of Defendant Johnson & Johnson located in Somerville, New Jersey. It is a foreign corporation licensed to do business in the State of Massachusetts.

4. At all times relevant herein, Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including, but not limite to, Prolift, Prolift +M, (hereinafter "Product" or the "Products"). Defendants manufactured, marketed, advertised, promoted and sold Pelvic Mesh Products worldwide.

5. All acts and omissions of each Defendant as described herein were done by its agents, servants, employees, representatives, and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

6. At all times hereinafter mentioned, Defendants were, and are currently, engaged in the business of designing, manufacturing, advertising, marketing, and selling mesh products, and in pursuance of this business, transacts business within the Commonwealth of Massachusetts and contracts to provide goods and services in the Commonwealth of Massachusetts.

7. At all times hereinafter mentioned, upon information and belief, Defendants committed tortious acts inside and outside the Commonwealth of Massachusetts, which caused injury to Plaintiff inside the Commonwealth of Massachusetts.

8. At all times hereinafter mentioned, upon information and belief, Defendants expect or should reasonably expect its acts to have consequences in the Commonwealth of Massachusetts and derives substantial revenue from interstate or international commerce.

II. JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1332(a) because Plaintiff and Defendants are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(a). A substantial portion of the events and omissions giving rise to this lawsuit occurred in this District and the Court has personal jurisdiction over each of the parties as alleged throughout this Complaint.

III. DEFENDANTS' PELVIC MESH PRODUCTS

11. On or about May, 2008, the Defendants began to market and sell a product known as Gynecare Prolift System, for the treatment of medical conditions in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. The Prolift System was and is offered as an anterior, posterior, or total repair system, and all references to the Prolift and/or Prolift System include by reference all variations.

12. Defendants' Pelvic Mesh Product was designed, patented, manufactured, labeled, marketed, sold and distributed by the Defendants, at all times relevant here.

IV. FACTUAL BACKGROUND

13. Plaintiff was diagnosed with uterine prolapse for which she underwent a total (anterior posterior) extraperitoneal sacral colpopexy (Prolift procedure) with a GYNECARE Prolift™ Total Pubic Floor Repair System on May 27, 2008. At this time she was implanted with a product manufactured and sold by Defendants. On January 6, 2017 plaintiff was required to undergo her first revision surgery for which she underwent excision of eroded vaginal mesh and excision of arm of the posterior mesh. On September 12, 2017 plaintiff underwent a second procedure for excision of mesh. On March 6, 2018 plaintiff underwent a third procedure for

excision of eroded mesh. On August 28, 2018 plaintiff underwent a fourth procedure for excision of mesh and division of scar tissue. On December 2, 2019 plaintiff underwent a fifth procedure for excision of vaginal vault scar, excision of small fragments of vaginal mesh and groin flap for closure of vaginal apical defect.

14. Surgical mesh products have been used to repair abdominal hernias since the 1950's. In the 1970's, gynecologists began using surgical mesh products designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990's, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Manufacturers, including Defendants, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and SUI. Defendants sold pelvic mesh "kits" which could include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Products manufactured by Defendants are considered Class II medical devices.

15. Defendants' Pelvic Mesh Products are targeted for women who suffer from pelvic organ prolapse and stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. These products are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele.

16. Moreover, these Pelvic Mesh Products contain polypropylene mesh. Despite claims that this material is inert, the scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' Pelvic Mesh Products. This immune response promotes

degradation of the polypropylene mesh, as well as the pelvic tissue, and can contribute to the formation of severe adverse reactions to the mesh.

17. At various times, Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. This clearance process did not require Defendants to prove the safety or efficacy of the Pelvic Mesh Products and, thus, a formal review of the safety and efficacy of the Pelvic Mesh Products was never conducted with regard to the Products. In the case of the Prolift product, Defendants marketed and sold the product for human implantation for over two years without the necessary clearance under Section 510(k).

18. Defendants' Pelvic Mesh Products have been marketed to the medical community and directly to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing Pelvic Mesh Products.

19. The Defendants have marketed and sold the Pelvic Mesh Products to the medical community at large and directly to patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and

misleading expectations as to the safety and utility of the Pelvic Mesh Products. Defendants' further engaged in direct-to-consumer marketing specifically designed to drive consumers to seek out these products for implantation into their bodies.

20. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of the Pelvic Mesh Products and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as a safe medical device when, in fact, Defendants knew that the Pelvic Mesh Products were not safe for their intended purposes and that the Pelvic Mesh Products would cause, and did cause, serious medical problems, and in some patients, catastrophic and permanent injuries. For example, Defendants described in its Patient Brochures, Instructions for Use, and other marketing materials, that the known complications for its Pelvic Mesh Products were consistent with any surgical procedure of an implantable medical device and described such occurrences as "rare" and "small" when in fact Defendants knew or should have known that the complications were not "rare nor small" but common, permanent, ant debilitating.

21. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Defendants' Pelvic Mesh Products have high malfunction, failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiffs, making them defective under the law. The Products' defects include, but are not limited to, the following:

a. the use of polypropylene material in the mesh itself and the immune reaction that results, causing adverse reactions and injuries;

b. in the case of the Prolift+M, the use of polypropylene in combination with monocryl, a partially dissolvable mesh that increases the immune reaction and inflammatory response;

c. the design of the Pelvic Mesh Products to be inserted transvaginally into an area of the body with high levels of bacteria, yeast, and fungus that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

d. the procedure itself, which is a part of the Pelvic Mesh Products, requires to the physician to insert the device "blindly," resulting in nerve damage and damage to other internal organs;

e. biomechanical issues with the design of the mesh that create strong amounts of friction between the mesh and the underlying tissue that subsequently cause that tissue to degrade resulting in injury;

f. the lack of porosity in the mesh resulting in the formation of a scar plate that prohibits tissue in-growth, resulting in mesh contraction, nerve damage, pain, and erosion of the mesh into other organs, and failure of the device;

g. the use and design of anchors in the Pelvic Mesh Products which when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

h. degradation of the mesh itself over time which causes the internal tissue to degrade resulting in injury;

i. particle loss and or "shedding" of the mesh both during implantation and following implantation that results in additional undesirable complications including an increased inflammatory response and a migration of those particles resulting in injury.

j. the welding and heating of the mesh itself during production which creates a toxic substance that contributes to the degradation of the mesh and host tissue alike;

k. the design of trocars, as devices to insert the Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries;

l. the propensity of the mesh for "creep", or to gradually elongate and deform when subject to prolonged tension inside the body;

m. the propensity of the mesh to contract, retract, and/or shrink inside the body;

n. the inelasticity of the mesh, causing them to be improperly matted to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and

o. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturer's instructions.

22. Upon information and belief, the Defendants have consistently underreported and withheld information about the propensity of Defendants' Pelvic Mesh Products to fail and cause injury and complications, and have misrepresented the efficacy and safety of the Pelvic Mesh Products, through various means and media, actively and intentionally misleading the FDA, the medical community, patients, and the public at large.

23. Defendants have further deliberately chosen to forgo the conduct of studies and registries to avoid reporting obligations that would be mandated under the federal regulations upon receipt of adverse event information.

24. Despite the chronic underreporting of adverse events associated with the Defendants' Pelvic Mesh Products, the underreporting of events associated with similarly designed competitor products, and Defendants' deliberately avoiding the conduct of studies and registries to avoid the reporting of adverse events, eventually enough complaints were recorded for the FDA to issue a public health notification regarding the dangers of these devices.

25. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to Pelvic Mesh Products. Although the

FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendants are one of the manufacturers of the Pelvic Mesh Products that are the subject of the notification.

26. On July 13, 2011, the FDA issued a Safety Communication: "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of Pelvic Organ Prolapse was an area of "continuing serious concern." (emphasis added) The FDA concluded that serious complication associated with surgical mesh for transvaginal repair of Pelvic Organ Prolapse, were "not rare." These serious complications include, but are not limited to neuromuscular problems, vaginal scarring/shrinkage and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization.

27. The FDA concluded in its Safety Communication that it was not clear that transvaginal repair of Pelvic Organ Prolapse with mesh or repair of SUI with mesh kits are more effective than traditional non mesh repair of pelvic organ prolapse. Further, the FDA conducted a systematic review of the published scientific literature from 1996–2011 and concluded that based thereon that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." The FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible."

28. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendants and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions for use, or labeling. In fact, at the time Defendants began marketing each of its Pelvic Mesh Products, Defendants were aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication.

29. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society (AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

30. On January 03, 2012, the FDA ordered postmarket surveillance studies ("522 studies") by manufacturers of urogynecologic surgical mesh devices to address specific safety and effectiveness concerns related to mini-sling devices for SUI and surgical mesh used for transvaginal repair of POP. This order was based on the FDA's evaluation of the published literature, analysis of adverse events reported to the FDA and feedback from the Obstetrics and Gynecology Devices Panel of the Medical Device Advisory Committee.

31. On April 29, 2014, the FDA issued two proposed orders for surgical mesh for transvaginal pelvic organ prolapse (POP) repair that put forth changes to address the risks

associated with these devices. One order proposed to reclassify surgical for transvaginal repair of POP from class II to III, and the second order proposed to require PMA applications for these devices. Once final, manufacturers will be required to provide clinical data in a premarket approval (PMA) application to support the safety and effectiveness of surgical mesh for transvaginal POP. Also, manufacturers of the tools specifically for implanting surgical mesh will be required to obtain premarket clearance (510(k)).

32. On January 5, 2016, the FDA finalized the proposed orders issued in 2014. As a result, the FDA reclassified surgical mesh for transvaginal repair of pelvic organ prolapse into class III, which require premarket approval (PMA) applications, the agency's most stringent device review pathway. The FDA mandated that premarket approval applications be filed by July 5, 2018 for any surgical mesh marketed for transvaginal pelvic organ prolapse repair. As a result of the FDA's actions, all manufacturers ceased marketing of surgical mesh intended for transvaginal repair of posterior compartment prolapse (rectocele).

33. On January 6, 2017, the FDA issued the final order reclassifying instrumentation for use with urogynecology surgical mesh from class II to III, requiring submission of 510(k)s for these devices.

34. On July 13, 2018, the FDA ordered the manufacturer of the last mesh surgical products on the market for the transvaginal repair of pelvic organ prolapse in the posterior compartment (rectocele) to stop selling and distributing their products.

35. On February 12, 2019, the FDA convened an advisory committee meeting to solicit input from experts on how to evaluate the safety and effectiveness of surgical mesh for transvaginal repair of prolapse. The panel concluded that to support a favorable benefit/risk, surgical mesh for transvaginal repair of prolapse should be superior to native tissue repair at 36

months, and the safety outcomes for surgical mesh for transvaginal repair of prolapse should be comparable to native tissue repair.

36. On April 16, 2019, the FDA ordered the two manufacturers of the three mesh surgical products on the market for the transvaginal repair of pelvic organ prolapse in the anterior/apical compartment (cystocele) to stop selling and distributing their products immediately.

37. Defendants knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

38. Defendants also knew or should have known that: (1) some of the predicate products for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices (including a medical device known as Protogen device); (2) that there were and are differences between the Defendants' Pelvic Mesh Products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; (3) that significant differences exist and existed between the Pelvic Mesh Products and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and (4) that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications.

39. The Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers and patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the Pelvic Mesh Products and the procedure for implantation were

and are safe and effective, leading to the prescription for and implantation of the Pelvic Mesh Products into Plaintiff.

40. Defendants' Pelvic Mesh Products are also defective due to Defendants' failure to adequately warn or instruct the Plaintiff and/or her health care providers of risks and complications including, but not limited to, the following:

a. the Products' propensities to contract, retract, and/or shrink inside the body;

b. the Products' propensities for degradation, fragmentation and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the Products' lack of porosity in preventing proper mating with the pelvic floor and vaginal region;

e. the rate and manner of mesh erosion or extrusion;

f. the risk of chronic inflammation resulting from the Products;

g. the risk of chronic infections resulting from the Products;

h. the risk of permanent vaginal or pelvic scarring as a result of the Products;

i. the risk of permanent vaginal shorting as a result of the Products;

j. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

k. the need for corrective or revision surgery to adjust or remove the Products;

l. the severity of complications that could arise as a result of implantation of the Products;

m. the hazards associated with the Products;

n. the Products' defects described herein;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

p. treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

q. treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

r. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

s. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

t. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain; and

u. the fact that neither pelvic organ prolapse, nor stress urinary incontinence, are life threatening conditions, and that other options, including non-surgical options, were available and superior alternatives to the use of the Products.

41. Defendants also failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of their Pelvic Mesh Products.

42. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products. Therefore, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Products.

43. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the Defendants' Pelvic Mesh Products.

44. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to the Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

45. Furthermore, the Defendants provide incomplete, insufficient, and misleading training and information to physicians, in order to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of the Pelvic Mesh Products, and also leading to the dissemination of inadequate and misleading information to patients, including Plaintiff.

46. The Pelvic Mesh Products implanted into the Plaintiff was in the same or substantially similar condition as it was when it left the possession of Defendants, and in the condition directed by and expected by the Defendants.

47. Plaintiff and Plaintiff's physicians foreseeably used and implanted the Pelvic Mesh Product and did not misuse or alter the Pelvic Mesh Product in an unforeseeable manner.

48. The injuries, conditions, and complications suffered by women who have been implanted with Defendants' Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), inability to engage in sexual relations, urinary problems, inability to void, blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, shortening of the vagina, pelvic floor damage, chronic pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women have been forced to undergo intensive medical treatment, including but not limited to, operations to locate

and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

49. The medical and scientific literature studying the effects of polypropylene pelvic mesh, like Defendants' Pelvic Mesh Products, have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

50. Defendants misrepresented to the medical and healthcare community, Plaintiffs, the FDA, and the public that the Pelvic Mesh Products had been tested and were found to be safe and effective for the purposes of treating incontinence and/or prolapse.

51. In the case of the Prolift device, Defendants misrepresented to the Plaintiff, to the Plaintiff's physicians, and to the medical community at large, that such product had been properly cleared for marketing by the FDA when in fact no such clearance had been sought or obtained.

52. These representations were made by Defendants with the intent of inducing the medical community, Plaintiff, and the public, to recommend, prescribe, dispense, and purchase the Pelvic Mesh Products for use as a means of treatment for stress urinary incontinence and/or prolapse, all of which evinced and indifference to the health, safety, and welfare of Plaintiff.

53. Defendants failed to undertake their duties to properly know the qualities of their Pelvic Mesh Products and in representations to Plaintiff and/or to Plaintiff's healthcare providers, and concealed and intentionally omitted the following material information:

a. That the Pelvic Mesh Products were not as safe as other products and procedures available to treat incontinence and/or prolapse;

b. that the Pelvic Mesh Products were not as effective as other products and procedures available to treat incontinence and/or prolapsed;

c. that the risk of adverse events with the Pelvic Mesh Products was higher than with other products and procedures available to treat incontinence and/or prolapse;

d. that the risk of adverse events with the Pelvic Mesh Products were not adequately tested and were known by Defendants;

e. that the limited clinical testing revealed the Pelvic Mesh Products had a higher risk of adverse effects, in addition to, and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

f. that Defendants failed to follow up on the adverse results from clinical studies and buried and/or misrepresented those findings;

g. that Defendants were aware of dangers in the Pelvic Mesh Products in addition to and above and beyond those associated with other products and procedures available to treat incontinence and/or prolapse;

h. that the Pelvic Mesh Products were dangerous and caused adverse side effects, including but not limited to higher incidence of erosion and failure, at a much more significant rate than other products and procedures available to treat incontinence and/or prolapse;

i. that patients needed to be monitored more regularly than usual while using the Pelvic Mesh Products and that in the event the Pelvic Mesh Products needed to be removed that the procedures to remove them had a very high failure rate and/or needed to be performed repeatedly; thus:

j. that the Pelvic Mesh Products were manufactured negligently;

k. that the Pelvic Mesh Products were manufactured defective; and

l. that the Pelvic Mesh Products were designed negligently, and designed defectively.

54. Defendants were under a duty to disclose to Plaintiff and Plaintiff's physicians, the defective nature of the Pelvic Mesh Products, including, but not limited to, the heightened risks of erosion, failure and permanent injury.

55. Defendants had sole access to material facts concerning the defective nature of the Pelvic Mesh Products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the Pelvic Mesh Products.

56. Defendants' concealment and omissions of material fact concerning the safety of the Pelvic Mesh Products were made to cause the Plaintiff, the Plaintiff's physicians and healthcare providers to purchase, prescribe, and/or dispense the Pelvic Mesh Products; and/or to mislead Plaintiff and Plaintiff's physicians into reliance and cause Plaintiff to have the Pelvic Mesh Products implanted into her body.

57. At the time these representations were made by Defendants, and at the time Plaintiff used the Pelvic Mesh Products, Plaintiff was unaware of the falsehood of these representations, and reasonably believed them to be true.

58. Defendants knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

59. In reliance upon these false representations, Plaintiff was induced to, and did use the Pelvic Mesh Product, thereby sustaining severe and permanent personal injuries and damages. Defendants knew or had reason to know that Plaintiff and Plaintiff's physicians and other healthcare providers had no way to determine the truth behind Defendants' concealment

and omissions, and that these included material omissions of facts surrounding the use of the Pelvic Mesh Product, as described in detail herein.

60. As a result of Defendants' research and testing or lack thereof, Defendants distributed false information, including but not limited to assuring Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that the Pelvic Mesh Products were safe for use as a means of providing relief from stress urinary incontinence and/or prolapse and were as safe or safer than other products and/or procedures available and on the market. Further, Defendants misrepresented to the Plaintiff and to the Plaintiff's physicians that the Pelvic Mesh Products were more effective than other means of treatment for these conditions for which they were implanted. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted, concealed and suppressed certain results of testing and research to healthcare professionals, Plaintiffs, and the public at large.

61. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public, Plaintiff, Plaintiff's healthcare providers, and the FDA.

62. The information distributed to the public, the medical community, the FDA, and Plaintiff by Defendants included, but was not limited to, reports, press releases, advertising campaigns, television commercials, print advertisements, billboards and other commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the Pelvic Mesh Products.

63. Defendants intentionally made material misrepresentations to the medical community and public, including Plaintiff, regarding the safety of the Pelvic Mesh Products specifically, that the Pelvic Mesh Products did not have dangerous and/or serious adverse health

safety concerns, and that the Pelvic Mesh Products were as safe as other means of treating vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

64. Defendants intentionally failed to inform the public, including Plaintiff, of the high failure rate including erosion, the difficulty of removing the mesh, and the risk of permanent injury.

65. Defendants chose to over-promote the safety, efficacy and benefits of the Pelvic Mesh Products instead.

66. Defendants' intent and purpose in making these misrepresentations was to deceive the public, the medical community, and Plaintiff; to gain the confidence of the public, the medical community, and Plaintiff; to falsely assure them of the quality and fitness for use of the Pelvic Mesh Products; and induce Plaintiff, the public and the medical community to request, recommend, prescribe, dispense, purchase, and continue to use the Pelvic Mesh Products.

67. Upon information and belief, Defendants made claims and representations in its documents submitted to the FDA and its reports to the public and to healthcare professionals and in advertisements that the Pelvic Mesh Products did not present serious health risks.

68. These representations, and others made by Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist and were made recklessly and without regard to the true facts.

69. These representations, and others made by Defendants, were made with the intention of deceiving the Plaintiff, Plaintiff's healthcare professionals and other members of the healthcare community, and were made in order to induce Plaintiff, and Plaintiff's healthcare professionals, to rely on misrepresentations, and caused Plaintiff to purchase, rely, use, and

request the Pelvic Mesh Products, and caused her healthcare professionals to dispense, recommend, or prescribe the Pelvic Mesh Products.

70. Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the Pelvic Mesh Products to the public at large, for the purpose of influencing the sales of Pelvic Mesh Products known to be dangerous and defective, and/or not as safe as other alternatives. Defendants utilized direct-to-consumer advertising to market, promote, and advertise the Pelvic Mesh Products.

71. At the time the representations were made, Plaintiff and Plaintiff's healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the Pelvic Mesh Products. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts or Defendants' misrepresentations.

72. Had the plaintiff known the true facts about the dangers and serious health and/or safety risks of the Pelvic Mesh Products, or in the case of the Prolift System, that the Defendants had not sought not obtained FDA clearance of the product, Plaintiff would not have purchased, used, or relied on Defendants' Pelvic Mesh Products.

73. At all times relevant herein, the Pelvic Mesh Products were widely advertised and promoted by the Defendants as a safe and effective treatment for vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele. Defendants minimized the risks posed to rectocele and vaginal prolapse patients with implantation of the Pelvic Mesh Products.

74. At all times relevant to this action, Defendants knew that the Pelvic Mesh Products were not safe for the patients for whom they were prescribed and implanted, because

the mesh eroded and otherwise malfunctioned, and therefore failed to operate in a safe and continuous manner, causing injuries including, but not limited to, erosion, extrusion, infection, sepsis, chronic foreign body invasion, dense adhesions and worsening dyspareunia. Removal of eroded or infected mesh brings a high rate of life-threatening complications including permanent disfigurement and hemorrhage. Removal can require multiple surgical interventions in the operating theater for complete removal and results in scarring on fragile compromised pelvic tissue and muscles.

75. Defendants failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

76. At all relevant times herein, Defendants continued to promote Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

77. In doing so the Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Pelvic Mesh Products for treatment of vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse or rectocele.

78. At all relevant times therein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiffs and the general public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products System including, but not limited to, mesh erosion, dense adhesions, worsening dyspareunia, chronic pain, infection, sepsis, permanent disfigurement and multiple surgeries for mesh removal.

79. The Pelvic Mesh Products as designed, manufactured, distributed sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions,

labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of pelvic health safety.

80. At all times herein mentioned, the employees, agents, officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned Pelvic Mesh Products when they knew of the hazards and dangerous propensities of said Pelvic Mesh Products, and thereby actively participated in the tortuous conduct that resulted in the injuries suffered by Plaintiff.

V. FRAUDULENT CONCEALMENT

81. Defendants' failure to document or follow up on the known defects in its product, and concealment of known defects, constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

82. Defendants are estopped from relying on the statute of limitations defense because Defendants actively concealed the defects, suppressing reports, failing to follow through on FDA notification requirements, and failing to disclose known defects to physicians. Instead of revealing the defects, Defendants continued to represent its Pelvic Mesh Products as safe for their intended use.

83. Defendants are and were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with their Pelvic Mesh Products. Because of Defendants' concealment of the true character, quality and nature of the Pelvic Mesh Products, Defendants are estopped from relying on any statute of limitations defense.

84. Defendants furthered this fraudulent concealment through a continued and systematic failure to disclose information to Plaintiff, physicians and the public.

85. Defendants' acts before, during and/or after the act causing Plaintiff's injury prevented Plaintiff from discovering the injury or cause thereof.

86. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

87. Defendants' conduct, as described in the preceding paragraphs, also amounts to a continuing tort, and continues up through and including the date of the filing of Plaintiffs' Complaint.

VI. CAUSES OF ACTION

COUNT I: DEFECTIVE MANUFACTURE AND DESIGN

Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

88. One or more of the defects in the Prolift Product implanted in Plaintiff are a result of improper or incorrect manufacturing processes that result in the Product as manufactured deviating from its intended design. The defects caused by improper or incorrect manufacturing rendered the Product unreasonably dangerous, deficient, and defective to consumers and to Plaintiff. The defects in the Product implanted in Plaintiff existed from its manufacture, therefore the defects were present when they left the possession and control of Ethicon.

89. Ethicon's Pelvic Mesh Product was defective, unfit, unsafe, inherently dangerous and unreasonably dangerous for its intended and reasonably foreseeable uses. The Product was in said condition when it entered the stream of commerce and was received by Plaintiff. The Product does not meet or perform to the expectations of patients and their health care providers.

Ethicon's Product was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

90. The Prolift Product created a risk to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Product.

91. Ethicon has intentionally and recklessly designed, manufactured, marketed, labeled, sold and distributed the Product with wanton and willful disregard for the health of the Plaintiff and others, and with malice, placing their economic interest above the health and safety of the Plaintiff.

92. The Product used by Plaintiff's physicians was not substantially changed, modified, or altered at any time in any manner whatsoever prior to use. The Prolift Product reached the Plaintiff in such a condition that was unreasonably dangerous to her. The Ethicon Prolift Product was used in the manner for which it was intended. This use resulted in injury to Plaintiff.

93. At no time did Plaintiff have reason to believe that the Prolift Product was in a condition not suitable for its proper and intended use among patients.

94. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defect of the Product. Furthermore, in no way could Plaintiff have known that Ethicon had manufactured the Product in such a way as to increase the risk of harm or injury to the patient receiving the implant.

95. As a direct and proximate result of Ethicon's wrongful conduct, including Ethicon's design, manufacture, labeling, marketing, sale and distribution of the Prolift Product,

Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering, and has incurred economic loss.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II: FAILURE TO WARN

Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

96. The Prolift Product was defective by reason of failure of Ethicon to provide an adequate warning or instructions.

97. Ethicon failed to properly and adequately warn and instruct the Plaintiff and/or her health care providers as to the risks and benefits of Ethicon's Prolift Product.

98. Ethicon failed to properly and adequately warn and instruct the Plaintiff and/or her health care providers with regard to the inadequate research and testing of the Prolift Product, and the lack of a safe, effective procedure for removal of the Product.

99. Ethicon failed to provide such adequate warning or instruction that a manufacturer exercising reasonable care would have provided to physicians who implanted the Prolift Product or to the women who had been implanted with the Product, concerning the following risks. Ethicon had actual or constructive knowledge of the following risks at the time the Product left Ethicon's control and were being marketed:

a. The high failure rate of the Product;

b. The high rate of infection and abscesses caused by the Product;

c. The high rate of vaginal erosions and extrusions caused by the Product;

d. The high rate of chronic pain caused by the Product;

e. The necessity to remove the Product from the patient's body in the event of product failure, infections, abscesses, erosion, extrusion, or other complications; and

f. The difficulty in removing the Product from the patient's body, including the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Product.

100. After receiving notices of numerous bodily injuries resulting from the Prolift Product, Ethicon failed to provide such post-marketing or post-sale warnings or instructions that a manufacturer exercising reasonable care should have provided to physicians who implanted the Product or those women who had been implanted with the Product that the products were causing an unreasonably high rate of complications such as mesh erosion, extrusion/protrusion, chronic pain, mesh contraction, infection, abscesses, fistula, inflammation, scar tissue, organ perforation, dyspareunia, bleeding, neuropathic and other acute and chronic nerve damage and pain, vaginal scarring, vaginal shrinkage, pelvic floor damage, pelvic pain, urinary and fecal problems, and prolapse organs. Furthermore, Ethicon failed to provide post-marketing or post-sale warnings or instructions concerning the necessity to remove the Product from the patient's body in the event of the product failure or other complications.

101. Ethicon intentionally, recklessly, and maliciously misrepresented the safety, risks and benefits of the Ethicon Prolift Product, understating the risks and exaggerating the benefits

in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

102. Absence of a warning or instruction renders the Product unreasonably dangerous for its intended use.

103. As a direct and proximate result of Ethicon's wrongful conduct, including Ethicon's wrongful design, manufacture, marketing, sale and distribution of the pelvic Mesh Product, both at the time of marketing and after the sale of the Prolift Product, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, serious bodily injury, mental and physical pain and suffering and has incurred economic loss.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III: NEGLIGENCE

Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

104. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, researching, manufacturing, marketing, labeling, packaging, supplying, distributing and selling the Prolift Product.

105. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Prolift Product. Defendants breached their duty by:

a. Failing to design the Product so as to avoid unreasonable risk of harm to women in whom the Product were implanted, including Plaintiff;

b. Failing to manufacture the Product so as to avoid an unreasonable risk of harm to women in whom the Product were implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Product so as to avoid an unreasonable risk of harm to women in whom the Product were implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Product so as to avoid an unreasonable risk of harm to women in whom the Product were implanted, including Plaintiff;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Product.

106. The reasons that Defendants' negligence caused the Product to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material in the Prolift Product and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Product to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Product, including, but not limited to, the propensity of the Product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Product, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Product for migration or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Product, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. the propensity of the Product for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the propensity of the Product to cause long standing inflammatory response altering the effective porosity of the mesh resulting in poor outcomes including bridging fibrosis, compromise of tissues in contact with or surrounding the mesh, erosion, nerve damage and resulting neuromas.

i. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

107. Defendants also negligently failed to warn or instruct the Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Prolift Product's propensities to contract, retract, and/or shrink inside the body;

b. The Product's propensities for degradation, fragmentation and/or migration;

c. The Product's inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The frequency and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Product;

f. The risk of chronic infections resulting from the Product;

g. The risk of permanent vaginal or pelvic scarring as a result of the Product;

h. The risk of de novo urinary dysfunction;

i. The risk of de novo dyspareunia or painful sexual relations;

j. The risk of recurrent, intractable pelvic pain and other pain resulting from the Product;

k. The need for corrective or revision surgery to adjust or remove the Product which in some cases is not feasible nor possible;

l. The severity of complications that could arise as a result of implantation of the Product;

m. The hazards associated with the Product;

n. The Product's defects described herein;

o. Treatment of pelvic organ prolapse and stress urinary incontinence with the products is no more effective than feasible, available and safer alternatives;

p. Treatment of pelvic organ prolapse and stress urinary incontinence with the Product exposes patients to greater risk than feasible, available and safer alternatives;

q. Treatment of pelvic organ prolapse and stress urinary incontinence with the Product makes future surgical repair more difficult than feasible, available and safer alternatives;

r. Use of the Product puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

s. Removal of the Product due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

t. Complete removal of the Product may not be possible and may not result in complete resolution of the complications, including pain.

108. As a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge, and multiple corrective surgeries as a result of implantation of mesh.

109. Defendants likewise failed to conduct post-market vigilance or surveillance by:

a. Monitoring or acting on findings in the scientific and medical literature;

b. Monitoring or investigating and evaluating reports in the FDA adverse event databases for their potential significance for Defendants' Prolift Product; and

c. Failing to comply with manufacturer requirements of the Medical Device Reporting (MDR) Regulations, specifically:

i. Failing to report MDRs (Medical Device [adverse event] Reports); and

ii. Failing to investigate reports of serious adverse events.

110. As a direct and proximate result of Defendants' negligence, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV: BREACH OF EXPRESS AND IMPLIED WARRANTIES

Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

111. Plaintiff was an individual whom Defendants could reasonably have expected to use, consume, or be affected by Defendants' Prolift Product within the meaning of Massachusetts General Laws ch. 106 §2-318.

112. In the design, manufacturing, marketing, distribution and sale of Defendants' Prolift Product, Defendants expressly and impliedly warranted to Plaintiff, her physicans and the general public that the Product was of merchantable quality and reasonably fit and safe for the ordinary purposes for which it was used and that the Products conformed to the standards imposed by law and were safe when used as intended.

113. Plaintiff, individually and/or by and through her physicians, reasonably relied upon Defendants' express and implies warranties and guarantees that the product was safe, merchantable and reasonably fit for its intended purposes.

114. Defendants breached these warranties because the Prolift Product implanted in Plaintiff was unreasonably dangerous and defective as described herein and not as Defendants had represented.

115. Defendants' breach of their express and implies warranties resulted in the implantation of an unreasonably dangerous and defective product in the body of the Plaintiff, placing the Plaintiff's health and safety in jeopardy.

116. The Product defects alleged herein were a substantial contributing cause of the injuries and damages suffered by Plaintiff.

117. As a result of Defendants' breach of the express and implied warranties, Plaintiff suffered and will continue to suffer injuries, damages, and losses as alleged herein.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V: NEGLIGENT MISREPRESENTATION

Plaintiffs incorporate by reference each and every paragraph of this Complaint as if fully set forth herein.

118. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Prolift Product had not been adequately

tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

119. Defendants failed to exercise ordinary care in the representations concerning the Prolift Product while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Product's high risk of unreasonable, dangerous, adverse side effects.

120. Defendants breached their duty in representing that the Defendants' Prolift Product has no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

121. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Prolift Product had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the Product, and other severe and personal injuries, which are permanent and lasting in nature.

122. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages together

with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI: VIOLATION OF CONSUMER PROTECTION LAW M.G.L. c. 93(A)

Plaintiffs incorporate all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

123. At all relevant times hereto the Defendants were engaged in trade or commerce.

124. The acts of the defendants alleged in Counts I through VI constitute unfair or deceptive acts or practices within the meaning of G.L. c. 93A, §§ 2 and 3, 940 C.M.R. 3.05(1), and 940 C.M.R. 3.16(1) and (2).

125. The actions of the Defendants described herein were performed willfully and knowingly.

126. As a result of the unfair or deceptive acts or practices described in Counts I through VI, the Plaintiff, DonnaRae Gordon, sustained injury including but not limited to the injuries detailed above, incorporated herein.

127. On December 3, 2019 the Plaintiff, through her attorneys, sent the Defendants, via UPS, a written demand for relief pursuant to M.G.L. c.93A, §9(3), identifying the claimant and reasonably describing the unfair and deceptive acts or practices relied upon and the injuries suffered.

128. As of the present date, 30 days have elapsed since service of Plaintiff's demand and there has been no satisfactory response by the Defendant, in violation of the requirements of M.G.L. c.93A §9. Defendants, via their counsel, denied Plaintiffs' claims and did not offer any form of settlement.

WHEREFORE, the Plaintiff demands judgment against the Defendants in an amount that is fair and reasonable plus treble such amount as provided by M.G.L. c. 93A § (9)(3); plus interest, costs, and attorney's fees to Plaintiffs; and award such other relief as the Court deems just and proper.

COUNT VII: LOSS OF CONSORTIUM

Plaintiffs incorporate all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

129. The Plaintiff, Thomas Gordon, is and at all relevant times, was the husband of Donna Rae Gordon.

130. As a direct and proximate result of the negligence of the Defendants, Thomas Gordon has suffered a diminution of his wife's love, affection, companionship, society and consortium.

WHEREFORE, Plaintiff, Thomas Gordon, demands compensatory damages, plus interest and costs.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

A. Judgment in favor of Plaintiffs and against Defendants, for damages in such amounts as may be proven at trial;

B. Compensation for both economic and non-economic losses, including but not limited to medical expenses, disfigurement, pain and suffering, mental anguish and emotional distress, in such amounts as may be proven at trial;

C. Compensation for loss of consortium in such amounts as may be proven at trial;

D. Attorneys' fees and costs where applicable;

E. Pre-and post-judgment interest; and

F. Judgment against the Defendants for count VI in an amount that is fair and reasonable; plus treble such amount as provided by M.G.L.c. 93A, sec.9(3); plus interest, cost, and attorneys' fees to plaintiffs.

JURY DEMAND

Plaintiffs hereby demand a trial by jury.

Respectfully submitted,

/s/ Marilyn T. McGoldrick
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DATED: